# LONGITUDINAL ANALYSIS OF PEDIATRIC (≥ 12 AND < 18 YEARS OLD) IN-CENTER HEMODIALYSIS PATIENTS: RESULTS FROM 2001 END-STAGE RENAL DISEASE (ESRD) CLINICAL PERFORMANCE MEASURES (CPM) PROJECT

**Supplemental Report #2**

2001 ESRD Clinical Performance Measures Project

*The Centers for Medicare & Medicaid Services* *February 2002*

## INTRODUCTION

The purpose of the ESRD Clinical Performance Measures (CPM) Project is to assist providers of End-Stage Renal Disease (ESRD) services in the assessment of care provided to ESRD patients and to stimulate improvement in that care. Beginning with the 2000 data collection effort, and again in 2001, clinical information was collected on all pediatric in-center hemodialysis (HD) patients in the U.S. aged 12 years up to, but not including, 18 years old.

This supplemental report is divided into two sections. In the first section, demographic characteristics and clinical information for several parameters of dialysis care including clearance, vascular access, management of anemia and serum albumin values are presented for two groups of patients: 1) the cohort of patients present in both the 2000 and the 2001 datasets (those patients included in both study years); and 2) the cohort of patients present only in the 2001 dataset. In the second section of this report, results of the longitudinal analysis of the parameters of dialysis care for those patients present in both datasets are presented.

## METHODS

All in-center HD patients aged ≥ 12 and < 18 years old identified by the 18 ESRD Networks as alive and receiving HD on December 31, 1999 and on December 31, 2000 were selected for inclusion in the 2000 and 2001 datasets, respectively.

### Data Collection

During May of each study year, a three-page data collection form was sent to each facility that had one or more HD patients ≥ 12 and < 18 years old dialyzing at that facility. Clinical information in the patients' medical records was abstracted for each patient who was receiving in-center HD during the months of October, November, and December, 1999 and October, November, and December, 2000 for the 2000 and 2001 datasets, respectively. Patient characteristic information collected included: gender, age, race, Hispanic ethnicity, years on dialysis, and primary cause of ESRD. The parameters of care examined included clearance, vascular access information, management of anemia, and assessment of serum albumin.

Clinical information used to assess the quality of care provided to these patients included the following: patient height and weight, pre- and post-dialysis blood urea nitrogen (BUN) values, dialysis session length to calculate Kt/V values, dialyzer KUf values, reported urea reduction ratios (URRs) and reported Kt/V values, type of vascular access, blood pump flow rates, monitoring of the access site for stenosis, hemoglobin (Hgb) values, prescribed Epoetin dose and route of administration, iron use and route of administration, transferrin saturation (TSAT) values, serum ferritin concentrations, and serum albumin values and the laboratory method used to determine them (bromcresol green [BCG] or bromcresol purple [BCP]).

Completed forms were returned to the appropriate Network office where data were reviewed and entered into a computerized database (Visual FoxPro). The data were aggregated by The Renal Network, Inc. and forwarded to The Centers for Medicare & Medicaid Services (CMS) for analysis.

### Data Analysis

For this report, a patient had to meet the following criteria to remain in the samples for analysis: a data collection form with at least one monthly hemoglobin value, at least one paired pre- and post-dialysis BUN value, and at least one serum albumin value over the three month study period. This case definition was identical to the one that has been used for the adult (≥ 18 years old) in-center HD sample over the course of the Project period (1993-2001). All available reported monthly values were utilized in calculating mean and median values. Kt/V values were calculated according to the Daugirdas II formula.[1]

Due to the small numbers of persons in racial categories other than black and white, analyses by race were limited to these two racial groups. Associations by age group compared patients 12-15 years old to patients 16 and < 18 years old. Causes of ESRD were categorized as congenital/urologic vs. other identified causes combined (FSGS, glomerulonephritis, SLE, hypertension or cystic disease) for some analyses. Associations of clinical data with patient characteristics were tested by Chi square, hierarchical ANOVA, and two-tailed Student's t-test and paired samples t-tests analyses were conducted. A p-value < 0.05 was considered to be significant.

The data analyses were conducted utilizing Epi Info, v. 6.04[2] and SPSS for Windows, v. 10.0.[3]

## RESULTS

### *Section I – Comparison of patients present in both datasets to patients only in the 2001 dataset*

433/486 (89%) of patients ≥ 12 and < 18 years old identified as receiving in-center HD as of December 31, 1999 were included in the 2000 study year's sample for analysis. 435/516 (84%) of patients identified as receiving in-center HD as of December 31, 2000 were included in the 2001 study year's sample for analysis. 188/435 (43%) of patients in the 2001 study year's sample for analysis were also present in the 2000 study year's sample for analysis.

Patient characteristics for both cohorts of patients (those patients present in both datasets and those patients only present in the 2001 dataset) are shown in Table 1. Patients present in both datasets were more likely to be black (48% vs. 38%, $p < 0.05$), older (16.1 years [±1.3 years] vs. 15.5 years [± 1.8 years], $p < 0.01$), and have congenital/urologic causes of ESRD (30% vs. 20%, $p < 0.05$) compared to patients present only in the 2001 dataset.

***Table 1:*** *Patient Characteristics*

| Patient Characteristics | Patients in both datasets | Patients in 2001 dataset only |
|---|---|---|
| | n (%) | n (%) |
| TOTAL | 188 (43) | 247 (57) |
| Gender | | |
| Male | 102 (54) | 128 (52) |
| Female | 85 (46) | 118 (48) |
| Race* | | |
| Black | 91 (48) | 94 (38) |
| White | 78 (41) | 121 (49) |
| Ethnicity | | |
| Hispanic | 38 (20) | 63 (26) |
| Non-Hispanic | 144 (77) | 170 (69) |
| Age (years) | | |
| Mean (± SD)** | 16.1 (± 1.3) | 15.5 (± 1.8) |
| Median | 16.1 | 16.0 |
| 12 to15 | 85 (45) | 121 (49) |
| 16 to < 18 | 103 (55) | 126 (51) |
| Primary Cause of ESRD* | | |
| Congenital/Urologic | 56 (30) | 49 (20) |
| Other causes combined | 74 (39) | 110 (45) |
| Duration of dialysis (years) | | |
| Mean (± SD)*** | 4.3 (± 3.8) | 2.1 (±3.0) |
| Median | 2.85 | 0.83 |
| Post-dialysis body weight | | |
| Mean (± SD) | 54.0 (± 19.6) | 57.0 (± 19.8) |
| Median | 48.3 | 52.9 |

Significant differences between groups noted by: * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

Note: Percents may not add up to 100% due to rounding.

### Clearance

The cohort of patients present in both datasets had a higher mean Kt/V compared to patients present only in the 2001 dataset (1.58 [± 0.30] vs. 1.45 [± 0.33], $p < 0.001$), and a higher percentage achieved a mean Kt/V ≥ 1.2 (93% vs. 78%, $p < 0.001$) (TABLE 2).

Dialysis session length was significantly longer for patients present in both datasets (212 min [±27 min] vs. 205 min [±29 min], $p < 0.05$). There was no significant difference in blood pump flow rates, nor any significant difference in the use of hi-flux dialyzers between the two groups.

### Vascular Access

A significantly larger percentage of patients present in both datasets were dialyzed with an AV fistula (AVF) or an AV graft compared to patients present only in the 2001 dataset (41% vs. 23%, for AVF; 34% vs. 17% for AV graft, $p < 0.001$) (TABLE 2). A significantly smaller percentage of patients present in both datasets were dialyzed with a catheter compared to patients present only in the 2001 dataset (25% vs. 60%, $p < 0.001$), and fewer were dialyzed with a catheter for 90 days or longer (20% vs. 39%, $p < 0.05$).

### Anemia Management

The mean hemoglobin was significantly higher for patients present in both datasets than for patients present only in the 2001 dataset (11.5 gm/dL [± 1.3 gm/dL] vs. 11.0 gm/dL [± 1.7 gm/dL], $p < 0.01$) (TABLE 2). 75% of patients present in both datasets compared to 55% of patients present only in the 2001 dataset achieved a mean hemoglobin ≥ 11 gm/dL ($p < 0.001$).

11% of patients present in both datasets were prescribed subcutaneous (SC) Epoetin compared to 8% of patients present only in the 2001 dataset ($p < 0.01$). There were no significant differences in the prescribed mean Epoetin dose between groups by either route of administration.

Although the mean TSAT value was not significantly different for the two groups, the percent of patients with a mean TSAT ≥ 20% was significantly higher in the group of patients present in both datasets compared to patients present only in the 2001 dataset (80% vs. 69%, $p < 0.05$). Mean serum ferritin concentration was significantly higher in the group of patients present in both datasets (443 ng/mL [± 347 ng/mL] vs. 297 ng/mL [± 322 ng/mL], $p < 0.001$). 82% of patients present in both datasets compared to 70% of patients present only in the 2001 dataset achieved a mean serum ferritin concentration ≥ 100 ng/mL ($p < 0.01$). Only 5% of patients present in both datasets had relative iron deficiency (defined for this report as both mean TSAT < 20% and mean serum ferritin concentration < 100 ng/mL) compared to 12% of patients present only in the 2001 dataset ($p < 0.05$).

Iron prescription patterns were similar for the two groups, with approximately 78% of patients prescribed iron at least

***Table 2:*** *Selected Intermediate Outcomes*

| Clinical Measure[a] | Pts in both datasets | Pts in 2001 dataset only |
|---|---|---|
| | **(n = 188)** | **(n=247)** |
| ***Clearance*** | | |
| Calculated Kt/V | | |
| Mean (± SD)*** | 1.58 (± 0.30) | 1.45 (± 0.33) |
| Median | 1.51 | 1.44 |
| Mean Kt/V ≥ 1.2*** | 152 (93) | 163 (78) |
| Calculated URR (%) | | |
| Mean (± SD)*** | 72.4 (± 6.1) | 69.8 (± 8.2) |
| Median | 71.9 | 70.8 |
| Mean URR ≥ 65%*** | 172 (92) | 185 (75) |
| Dialysis session length (minutes) | | |
| Mean (± SD)* | 211.5 (± 27.4) | 204.9 (± 28.7) |
| Median | 210 | 210 |
| Blood pump flow rate (mL/minute) | | |
| Mean (± SD) | 311.8 (± 80.4) | 297.3 (± 82.7) |
| Median | 300 | 300 |
| Dialyzed with hi-flux dialyzers (KUf ≥ 20 mL/mmHg/hr) | 62 (41) | 98 (47) |
| ***Vascular Access*** | | |
| Type of access*** | | |
| AV fistula | 77 (41) | 57 (23) |
| AV graft | 64 (34) | 42 (17) |
| Catheter | 47 (25) | 148 (60) |
| Catheter in use ≥ 90 days* | 37 (20) | 97 (39) |
| ***Anemia Management*** | | |
| Hemoglobin (gm/dL) | | |
| Mean (± SD)** | 11.5 (± 1.3) | 11.0 (± 1.7) |
| Median | 11.6 | 11.2 |
| Mean Hgb ≥ 11 gm/dL*** | 140 (75) | 135 (55) |
| Mean Hgb 11-12.0 gm/dL** | 78 (42) | 66 (27) |
| Mean Hgb 11-12.9 gm/dL*** | 126 (67) | 111 (45) |
| Mean Hgb < 9 gm/dL** | 12 ( 6) | 37 (15) |
| Mean Hgb < 10 gm/dL** | 25 (13) | 65 (26) |
| Patients prescribed Epoetin | | |
| Within this group: | 186 (99) | 239 (97) |
| Prescribed IV*** | 165 (89) | 223 (93) |
| Prescribed SC** | 20 (11) | 19 ( 8) |
| Weekly Epoetin dose (units/kg/week) | | |
| IV | | |
| Mean (± SD) | 275.8 (± 228.2) | 299.2 (±208.9) |
| Median | 210.8 | 250.0 |
| SC | | |
| Mean (± SD) | 239.3 (± 195.3) | 223.9 (± 187.4) |
| Median | 180.4 | 142.9 |
| Transferrin saturation (%) | | |
| Mean (± SD) | 30.3 (± 14.6) | 28.0 (± 13.8) |
| Median | 27.0 | 25.5 |
| Mean transferrin saturation ≥ 20%* | 138 (80) | 152 (69) |
| Serum ferritin concentration (ng/mL) | | |
| Mean (± SD)*** | 443.4 (± 346.8) | 296.9 (± 321.7) |
| Median | 372.0 | 198.0 |
| Mean serum ferritin ≥ 100 ng/mL** | 144 (82) | 153 (70) |
| Patients with relative iron deficiency[b]* | 10 (5) | 29 (12) |
| Patients prescribed iron | 144 (77) | 196 (79) |
| Within this group: | | |
| Prescribed IV | 109 (76) | 160 (82) |
| Prescribed PO* | 47 (33) | 61 (31) |
| ***Serum Albumin*** | | |
| BCG[c] | (n=148) | (n=198) |
| Mean (± SD)*** | 3.97 (± 0.41) | 3.74 (± 0.49) |
| Median | 4.03 | 3.80 |
| BCP[d] | (n=40) | (n=48) |
| Mean (± SD) | 3.67 (± 0.32) | 3.60 (± 0.41) |
| Median | 3.65 | 3.57 |
| Mean serum albumin ≥ 4.0/3.7 gm/dL*** (BCG/BCP) | 100 (53) | 88 (36) |
| Mean serum albumin ≥ 3.5/3.2 gm/dL** (BCG/BCP) | 170 (90) | 194 (79) |

Significant differences between groups noted by: * $p < 0.05$; ** $p < 0\ 01$; *** $p < 0.001$

[a] Continuous variables displayed as the mean (± SD) and median values; categorical variables displayed as number and percent of available values

[b] Relative iron deficiency defined for this report as a mean transferrin saturation < 20% and a mean serum ferritin concentration < 100 ng/mL

[c] BCG = bromcresol green laboratory method

[d] BCP = bromcresol purple laboratory method

once during the study period. Although a lower percentage of patients present in both datasets were prescribed intravenous (IV) iron, compared to patients only in the 2001 dataset, (76% vs. 82%) the difference was not statistically significant.

### Serum Albumin

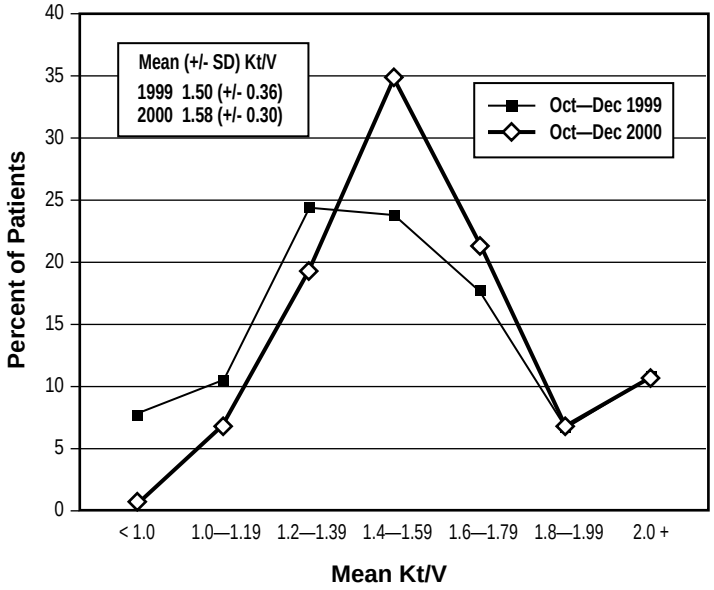
Mean serum albumin values were higher for the group of patients present in both datasets. 53% of patients present in both datasets had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) compared to 36% of patients present only in the 2001 dataset ($p < 0.001$) (TABLE 2).

## *Section II – Results for the Cohort of Patients in Both Datasets, Oct-Dec 1999 and Oct-Dec 2000*

### Clearance

Mean Kt/V increased from 1.50 (±0.36) to 1.58 (± 0.30) for these patients from Oct-Dec 1999 to Oct-Dec 2000 ($p < 0.01$) (FIGURE 1, TABLE 3). In late 1999, 28 patients had a mean Kt/V < 1.2. By late 2000, 20/28 (71%) had achieved a mean Kt/V ≥ 1.2.

***Figure 1:*** *Distribution of mean Kt/V values for patients in both datasets, late 1999 to late 2000.*




Mean dialysis session length increased for these patients from late 1999 to late 2000 (207 min (± 28 min) to 211 min (± 27 min), $p < 0.01$. Mean blood pump flow increased significantly ($p < 0.05$) for all access types over the two study periods (TABLE 3).

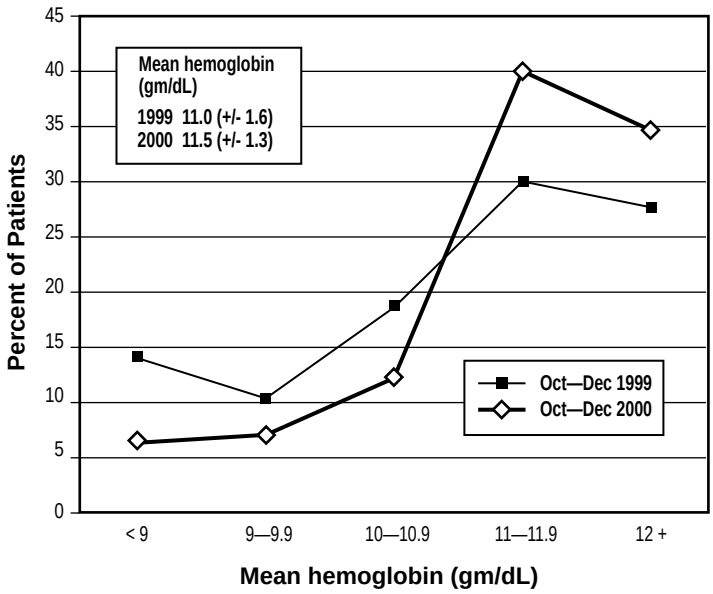
### Vascular Access

In late 1999, 68 patients were dialyzed with a catheter. In late 2000, 19/68 (28%) of these patients were dialyzed with an AVF and another 11/68 (16%) were dialyzed with an AV graft.

### Anemia Management

The mean hemoglobin increased for this group of patients from late 1999 to late 2000 (from 11.0 gm/dL [± 1.6 gm/dL] to 11.5 gm/dL [± 1.3 gm/dL], $p < 0.001$) (FIGURE 2, TABLE 3). 49/80 (61%) of patients who had a mean hemoglobin < 11 gm/dL in late 1999 had a mean hemoglobin ≥ 11 gm/dL in late 2000. 34/45 (76%) of patients who had a mean hemoglobin < 10 gm/dL in late 1999 had a mean hemoglobin ≥ 10 gm/dL by late 2000.

***Figure 2:*** *Distribution of mean hemoglobin for patients in both datasets, late 1999 to late 2000.*




Mean Epoetin doses did not change significantly for these patients over the two study periods by either route of administration.

28/43 (65%) of patients who had a mean TSAT < 20% in late 1999 had a mean TSAT ≥ 20% by late 2000.
34/49 (69%) of patients who had a mean serum ferritin concentration < 100 ng/mL in late 1999 had a mean serum ferritin concentration ≥ 100 ng/mL by late 2000.

Although the percent of patients prescribed IV iron increased from 53% to 58% from late 1999 to late 2000, the difference was not statistically significant.

### Serum Albumin

Mean serum albumin by the BCG laboratory method increased significantly from late 1999 to late 2000 (from 3.83 gm/dL [± 0.54 gm/dL] to 3.95 gm/dL [± 0.42 gm/dL], $p < 0.01$). 31/105 (30%) of patients who had a mean serum albumin < 4.0/3.7 gm/dL (BCG/BCP) in late 1999 had a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP) by late 2000.

*Table 3: Change in measures for patients in both datasets from late 1999 to late 2000*

| Clinical characteristic | n | Oct-Dec 1999 | Oct-Dec 2000 | p-value |
|---|---|---|---|---|
| ***Clearance*** | | | | |
| Mean calculated Kt/V | 149 | 1.50 (± 0.36) | 1.58 (± 0.30) | < 0.01 |
| Mean calculated URR (%) | 188 | 70.3 (± 9.1) | 72.4 (± 6.1) | < 0.001 |
| Mean reported Kt/V | 127 | 1.53 (± 0.33) | 1.61 (± 0.27) | < 0.01 |
| Mean reported URR (%) | 166 | 69.6 (± 8.5) | 72.1 (± 5.6) | < 0.001 |
| Mean dialysis session length (minutes) | 184 | 207.0 (± 28.3) | 211.2 (± 27.4) | < 0.01 |
| Mean blood pump flow (mL/minute) | | | | |
| AVF | 51 | 308.6 (± 62.4) | 329.9 (± 60.4) | < 0.05 |
| AV graft | 35 | 309.2 (± 92.7) | 335.1 (± 81.6) | < 0.05 |
| Catheter | 34 | 250.4 (± 97.2) | 278.6 (± 78.1) | < 0.05 |
| ***Anemia Management*** | | | | |
| Mean hemoglobin (gm/dL) | 188 | 11.0 (± 1.6) | 11.5 (± 1.3) | < 0.001 |
| Mean TSAT (%) | 151 | 27.8 (± 15.1) | 31.3 (± 15.0) | < 0.05 |
| Mean serum ferritin (ng/mL) | 156 | 286 (± 278) | 460 (± 353) | < 0.001 |
| Mean weekly Epoetin dose (units/kg/week) | | | | |
| IV | 130 | 272.9 (± 185.7) | 269.7 (± 222.4) | =0.853 |
| SC | 17 | 183.7 (± 104.4) | 241.1 (± 184.8) | =0.081 |
| ***Serum Albumin*** | | | | |
| Mean serum albumin (gm/dL) | | | | |
| BCG | 135 | 3.83 (± 0.54) | 3.95 (± 0.42) | < 0.01 |
| BCP | 30 | 3.64 (± 0.34) | 3.66 (± 0.25) | =0.733 |

## KEY OBSERVATIONS

• Patients present in both datasets were more likely to be black, and have congenital urologic disease as their underlying renal diagnosis than those patients present only in the 2001 study year.

• Compared to patients present only in the 2001 study year, patients present in both datasets had significantly better parameters of dialysis care in several areas including mean Kt/V, percentage of patients with a mean Kt/V ≥ 1.2, percentage of patients dialyzed with an AV fistula or graft, mean hemoglobin, percentage of patients achieving a mean hemoglobin of ≥ 11 gm/dL, mean serum albumin and percentage of patients with a mean serum albumin ≥ 4.0/3.7 gm/dL (BCG/BCP).

• When the clinical parameters from each study year were compared in the 188 patients present in both datasets, significant improvements were also seen, including increased mean Kt/V, increased mean hemoglobin and increased mean serum albumin by the BCG laboratory method.

• In those patients present in both datasets whose clinical parameters failed to meet adult DOQI guidelines in the 2000 study year, a substantial percentage had parameters that met those guidelines in the 2001 study year.

## NEXT STEPS

• CMS will continue to collect data on adolescent pediatric hemodialysis patients, which will provide longitudinal data on a subset of these patients who remain on hemodialysis.

• Further analysis of these data will be conducted to more fully describe areas where improvement in clinical care have been achieved, as well as to understand where opportunities for further improvement in patient care exist.

## REFERENCES

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